HISTORY OF NEGATIVE PRESSURE PARTICULATE RESPIRATOR CERTIFICATION

I. INTRODUCTION:

A. When discussing the history of particulate respirator approval, focus on the Bureau of Mines is essential because this is where respirator certification originated. The Bureau of Mines came into existence because of hazardous mining conditions. From the years 1839 to 1992, 15,183 miners were killed in 716 mining disasters.

B. In Figure 1, from reference (a), mine rescuers are at a barricade behind which they found surviving miners after a mine explosion in Briceville, TN on 9 December 1911. This barricade had reached to the ceiling but was torn down by the rescuers. Notice they are very interested in observing the reaction of a canary to the atmosphere. Canaries would visibly show distress and sway on their perches in the presence low concentrations of carbon monoxide and other gases before toppling over. It is not just mining disasters that kill miners. Every year 1,500 miners die from “Black Lung” disease caused by inhalation of coal dust. To help put this number of Black Lung disease deaths in perspective, there were 1,500 lives lost as result of the sinking of the Titanic. Adults were not the only casualties. Miners started to work as young as eight years old (Figure 2, from reference (a)).

Figure 1

Figure 2

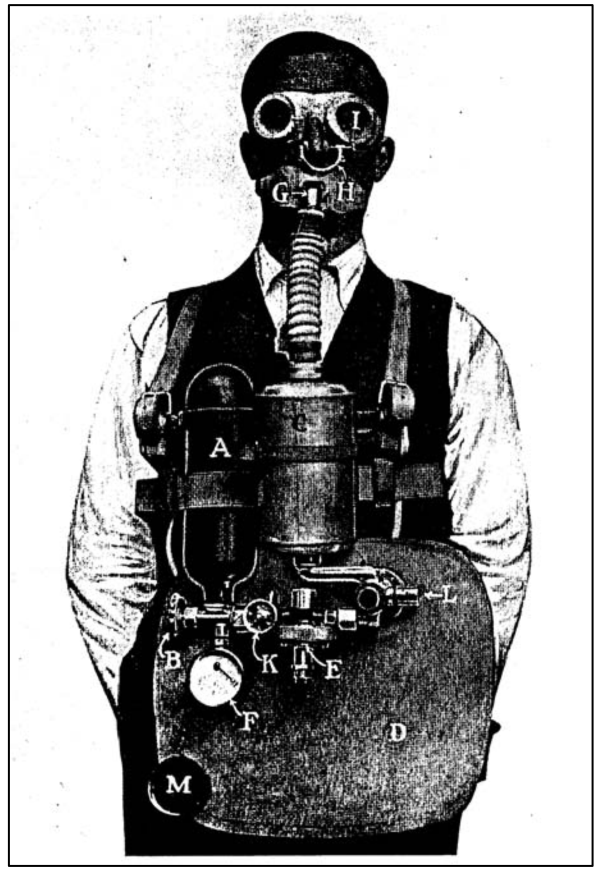


Figure 3

C. In 1907, the Secretary of the Interior established the Technologic Branch in the U.S. Geological Survey to aid the mineral industry with health and safety problems. In 1910 Congress removed the Technologic Branch from the U.S. Geological Survey and established the Bureau of Mines within the Department of the Interior. The Bureau of Mines mission was to contend with an alarming number of fatalities and injuries in coal mines.

II. EARLY EVOLUTION OF RESPIRATORS:

A. The Bureau of Mines developed technology to minimize mine accidents, primarily from coal dust and methane gas explosions. The mining equipment industry refined and marketed many of the technologies developed by Bureau of Mines. According to reference (b), two Bureau of Mines engineers (John Ryan and George Deike) created the Mine Safety Appliances Company in 1914. Figure 3, from reference (b), is a closed circuit, self-contained breathing apparatus or SCBA developed for mine rescue from the 1917 MSA catalog.

B. According to reference (b), Schedule 14 for gas masks went into effect in August 1919, however, the Bureau of Mines didn't start approving particulate filtering respirators until 1934 under schedule 21, and it wasn't until 1944 that Chemical cartridge respirators started being approved under schedule 23. Nevertheless, prior to that time particulate respirators and chemical cartridge respirators were manufactured and sold – they were just not certified. There were many interesting devices designed during the early evolution of respirators as shown in figures 4 through 7 from reference (b). Figures 4 and 5 show a half mask and a full face particulate filtering respirator from the 1917 MSA Catalog. Figure 6 is a 1923 Wilson dust respirator which used a sponge for a filter. When it became dirty, it could be rinsed out and reused. Figure 7 contains a picture of a 1929 American Optical vapor respirator. Can you imagine what kind of sound was produced from breathing out through this large rubber exhalation valve?

Figure 4

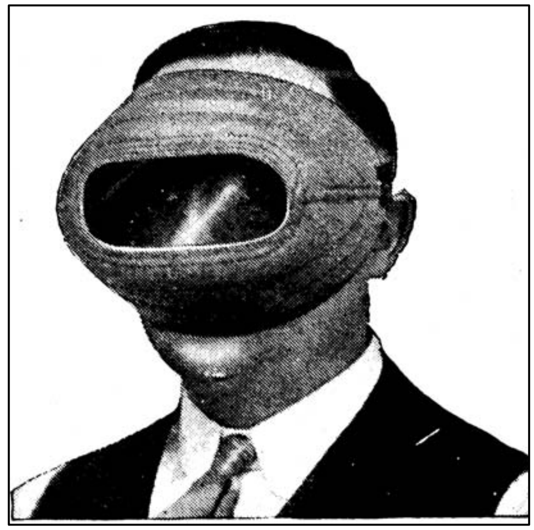


Figure 5

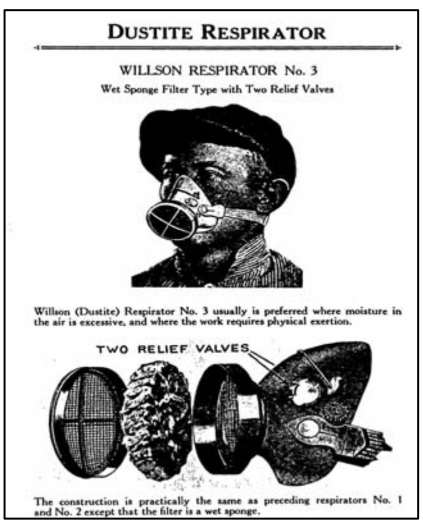


Figure 6

Figure 7

C. The Bureau of Mines experimented with many respirator designs. Figure 8 is a 1924 creation of the Bureau of Mines, called the Kilman's cap-style dust respirator. The filter is worn on the top of the head. This provides quite a large surface area for the filtering media. For some reason this design did not catch on with the public.

D. <u>Mine Rescue:</u> The Bureau of Mines was very active in mine safety in other ways in addition to respirator certification testing and approval. The Bureau of Mines had mine rescue teams. Figure 9, from reference (a), shows two mine rescuers prepared for a mine rescue operation and equipped with a canary in what was called a "resuscitation" cage. Figure 10, from reference (a), is a picture of a 1926 Bureau of Mines device for demonstrating the effect of carbon monoxide on canaries. Is this kind of like calibrating canaries?

Figure 8

Figure 9

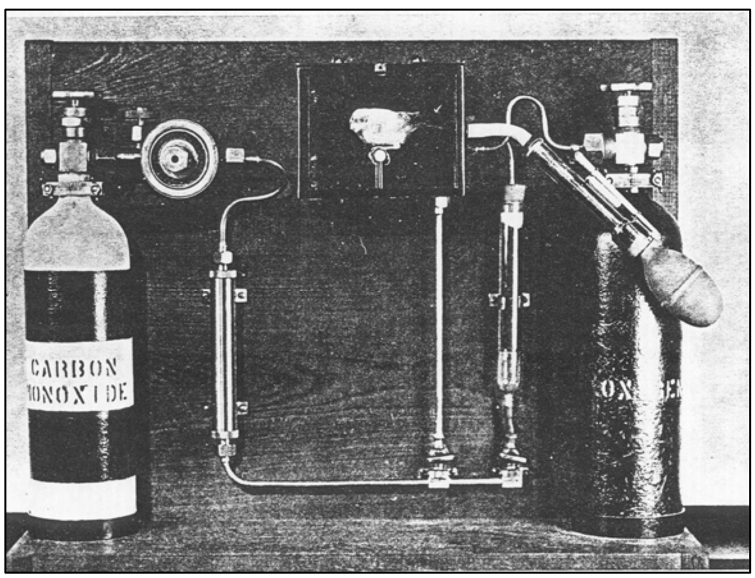


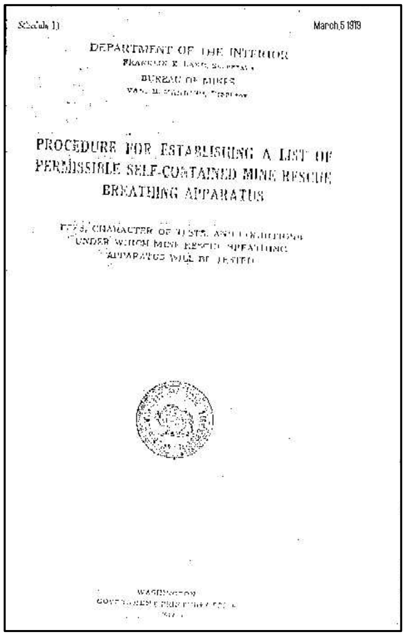
Figure 10

E. In March 1917, the War Gas Investigations Branch was established in the Bureau of Mines to research use of toxic gas as an instrument of war and to develop chemical warfare defense. However, this was short lived. President Wilson transferred the laboratories set up for the Bureau of Mines to the War Department and on 28 June 1918 the War Department established the Chemical Warfare Service, which was given full responsibly for toxic chemical warfare and defense. Figure 11, from reference (b) shows the range of design of World War I military gas masks. Bureau of Mines returned to its primary mission of mine safety research and on 5 March 1919 established Schedule 13 for certifying Self Contained Breathing Apparatus for mine rescue. The cover of this first respirator schedule is show in Figure 12 (courtesy of Don Campbell, from NIOSH).

Figure 11

F. First Respirator Approvals and a Scandal: Bureau of Mines issued its first respirator approval to the Gibbs respirator manufactured by MSA on 15 January 1920. The approval number was BM-1300, for the first SCBA approved under Schedule 13. This respirator, shown in Figure 13, from reference (b), was a closed circuit SCBA which operated on compressed oxygen and a soda lime scrubber to remove carbon dioxide.

1. In 1925, as result of the Teapot Dome Scandal (Figure 14), the Bureau of Mines was transferred to the Department of Commerce. Albert Fall, the Secretary of the Department of Interior made a secret arrangement in which the U.S. naval petroleum reserve at Wyoming's Teapot Dome was leased without competitive bidding to a private oil company. Secretary Fall received $400,000.00 in bribes and loans. More information is available concerning this issue at the following websites Teapot / Dome.



March 5 1919

DEPARTMENT OF THE INTERIOR

BUREAU OF MINES

PROCEDURE FOR ESTABLISHING A LIST OF PERMISSIBLE SELF-CONTAINED MINE RESCUE BREATHING APPARATUS

CHARACTER OF TESTS AND CONDITIONS UNDER WHICH MINE RESCUE BREATHING APPARATUS WILL BE TESTED

Figure 12

Figure 13

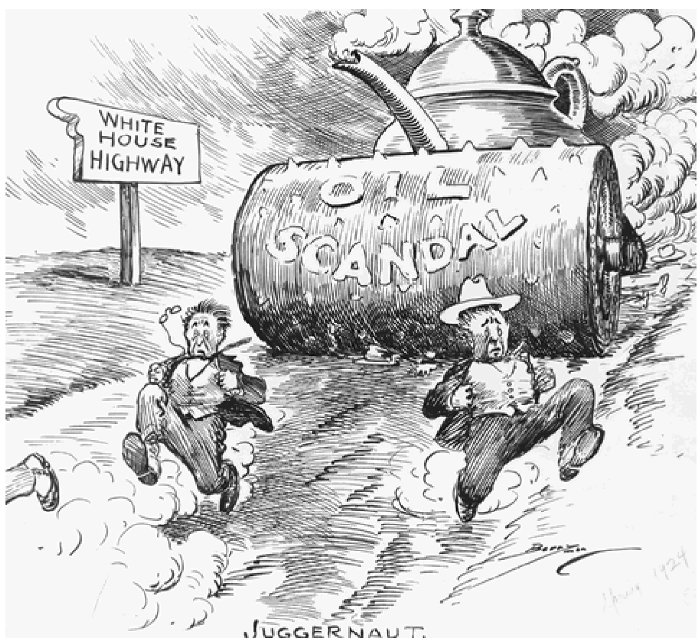


Figure 14

2. The American public was very upset over this long and drawn out investigation. Secretary Fall was found guilty of bribery; was fined $100,000.00; and spent one year in jail. Through guilt by association, the Bureau of Mines also suffered. It was transferred to the Department of Commerce and its funding was progressively cut. After America's emotions cooled down over this incident, the Bureau of Mines was returned to the Department of the Interior in 1934.

III. 30 CFR 14, SCHEDULE 21 OF 1934 - DUST, FUME, AND MIST RESPIRATORS:

A. In 1934, Schedule 21 was established setting forth procedures for testing filter-type Dust, Fume, and Mist Respirators. Schedule 21 was modified five times over the years. Certification testing was conducted at the Pittsburgh Experiment Station.

1. Type A respirators protected against mechanically generated dusts, such as dust clouds produced in mining, quarrying and tunneling operations and various industrial grinding, crushing, and mineral processing.

2. Type B protected against fumes of metals, such as lead, manganese, copper, chromium, iron, antimony, and arsenic resulting from condensation of their vapor or from chemical reactions between their vapor and gases.

3. Type C protected against mists produced by spray painting, chromic acid mists from plating, and mists of other materials whose liquid does not produce harmful vapors.

4. Types AB, AC, etc. were combinations of Types A, B, and C.

B. Figure 15 (courtesy of Don Campbell, from NIOSH) is a picture of test subjects after one of the "Man Tests" called the coal dust test. The coal dust test consisted of three men with full, average, and lean facial features exercising in a room containing a visible atmosphere of airborne powdered bituminous coal. The test subjects alternated walking at the rate of 3.5 mph for five minutes with sitting for five minutes for a total of 30 min. At the end of the test, forced nasal discharge, sputum, nasal cavities, and the part of the face covered by the respirator must not show appreciably more visible coal dust than similar observations made before entering the coal dust atmosphere.

Figure 15

C. Mechanical Airflow resistance of the complete respirator assembly was tested at the flow rate was 85 lpm (liters per minute), which is the same as today's certification tests in 42 CFR 84. Like today's certification standard, exhalation resistance could not exceed 25 mm H_2O. In contrast, the inhalation resistance could be up to 50 mm H_2O as compared with the present 35 mm H_2O requirement.

D. Respirators approved as Type A for Dust were mechanically tested at 32 lpm in an atmosphere of 0.6 micron sized free silica produced from ground flint. There were two tests: High Dust and Low Dust Concentrations. In the High Dust Test, three respirators were tested for three 30 minute periods in 50 mg/m^3 silica atmosphere. Leakage must not exceed 9 mg for the three respirators or 4 mg for any one of them. In the Low Dust Concentration Test, three respirators were tested for two 156 minute periods in 5 mg/m^3 silica atmosphere. Leakage must not exceed 30 mg for the three respirators or 12 mg for any one respirator

E. There were two types of Type B Fume Respirators - "Low Filter Plugging Fumes" and "Fast-Plugging Fumes." Low Filter Plugging Fumes do not cause appreciable increase in filter air flow resistance such as lead, manganese, copper, and chromium fumes. These respirators were mechanically tested at 32 lpm in an atmosphere of 15 mg/m^3 lead oxide fume produced by decomposition and combustion of tetraethyl lead. Leakage in each respirator could not exceed 1.5 mg. Fast-Plugging Fumes such as magnesium, zinc, cadmium, aluminum, and antimony, which significantly increase filter resistance. Fast-Plugging Fume respirators first had to pass the Low-Plugging Fumes Test then pass an additional test. In this test, three respirators were tested at 32 lpm in 100 mg/m^3 magnesium oxide produced by burning magnesium ribbon. These respirators were tested until 200 mg magnesium oxide was pulled through the filters. Then they had to pass the Mechanical Airflow resistance Test with maximum inhalation and exhalation resistance of 50 and 25 mm H_2O, respectively.

F. Type C Mist respirators had three tests. In the Chromic Acid Mist Test, respirators were tested at 32 lpm in 15 mg/m^3 chromic acid mist produced by electrolyzing an aqueous solution of chromic acid. Three respirators were tested for two 156 minute periods. Leakage could not exceed 1 mg for any one respirator. Passing this test would gain chromic acid mist approval. For approval as protection against all mist the next two tests must be passed.

1. Lead-Paint Mist Test: Respirators were tested at 32 lpm in 300 to 600 mg/m^3 lead spray paint mist. Three respirators were tested for two 156 minute periods. Leakage could not exceed 1.5 mg lead for any one respirator.

2. Water-Mist, Silica Dust Test: Respirators were tested at 32 lpm in 10 mg/m^3 aqueous silica mist. Three respirators were tested for two 156 minute periods. Leakage could not exceed 5 mg silica for any one respirator.

IV. 30 CFR 13, SCHEDULE 14E OF 1941 - GAS MASKS:

A. Gas masks are mentioned because they can be approved with particulate filters. Schedule 14 had been around since 1919 and has been modified eight times, but the information here is from the 1941 version, Schedule 14E.

B. Besides being tested for gases and vapors, the respirators with particulate approvals had to meet the Schedule 21 requirements for Dusts, Fumes, and Mist. In addition, the canisters had to filter out "specially prepared" tobacco smoke when exposed to an 85 lpm simulated breathing rate. Schedule 14 did not state how to prepare the tobacco smoke but it referenced a 1926 Bureau of Mines Technical Paper on how to prepare it.

C. Two separate particulate Man tests had to be passed. In the first test, two men performed exercises in a 1,000 cubic foot room filled with smoke from one pound of cotton waste burning in a smudge pot. To pass the 10 minute test, no respiratory or eye discomfort or irritation could be experienced.

D. In the second test, a 20 minute test, two men had to perform exercises in a 500 ppm tin tetrachloride atmosphere without experiencing irritation of the eyes and respiratory system. Tin tetrachloride forms hydrogen chloride with the moisture in the respiratory system, which is very irritating.

V. 30 CFR 14A, SCHEDULE 23 OF 1944 - NON-EMERGENCY GAS RESPIRATORS:

A. On 13 November 1944, Bureau of Mines published Schedule 23 for organic vapor respirators for use in non-immediately dangerous to life or health (IDLH) atmospheres of organic vapors up to concentrations of 1,000 ppm or 0.1%. As implied above, the 1944 version of this standard was limited in scope to only organic vapor respirators. However, particulate filters were used in combination with many organic vapor respirators. These combination cartridge respirators had to pass some interesting tests.

B. This schedule approved two types of respirators: Type B and Type BE. Type B respirators were approved for protection against organic vapors only. Cartridges were tested for their efficacy against a challenge concentration of 1,000 ppm carbon tetrachloride.

1. Type BE respirators were approved for protection against organic vapors and dusts, fumes, and mists.

   a. The BE respirators had to pass the Type A, B, C, or D tests under schedule 21 for Dust, Fume and Mist.

C. In addition, two man tests were conducted for the organic vapors. The first was a "tightness test" where two men exercised while wearing the respirators in 100 ppm isoamyl acetate, which is similar to the current qualitative banana oil fit test.

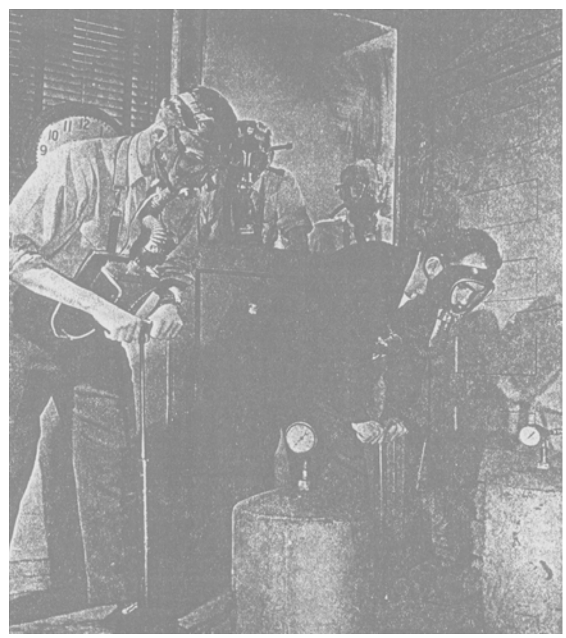


FIGURE 16

D. In the second test, the respirators were tested against a 5,000 ppm carbon tetrachloride atmosphere in which two men wore the respirators until the odor of carbon tetrachloride was detected inside the respirator. A series of exercises were performed including the one shown in Figure 16, from reference (b), in which the test subjects pumped air with a hand operated tire pump into a one cubic foot cylinder to a pressure of 25 psi. The chemical cartridges had to last at least 30 minutes to pass the test. Even though the test was performed under high concentrations, approval was still granted for organic vapor concentrations not exceeding 1,000 ppm. 5,000 ppm of carbon tetrachloride was used instead of 1,000 ppm to speed up the test by about five times. NIOSH now considers 200 ppm carbon tetrachloride as IDLH. These man tests were conducted in 25 times the current IDLH concentration for carbon tetrachloride!

VI. 30 CFR 14, SCHEDULE 21A, OF 1955 – REVISED DUST, FUME, AND MIST RESPIRATORS:

A. In 1954, Schedule 21 was revised to Schedule 21A. For the first time, single use respirators were first approved. Unlike reusable respirators in which filters could be changed, single use respirators were designed for disposal after use. There were two classes of single use respirators.

1. Approved against Pneumonoconiosis producing dust and nuisance dust but not for Fumes.

    a. Pneumonoconiosis is a disease of the lungs caused by the habitual inhalation of mineral or metallic particles.

2. Approved against dusts that were no more toxic than lead.

B. Schedule 21A also included certification testing for respirators with replaceable filters for protection against the inhalation hazards listed here.

1. Pneumoconiosis producing and nuisance dust
2. Toxic dust
3. Dusts
4. Fumes
5. Silica mist
6. Chromic acid mist
7. Combination approval

C. The facepieces of all respirator categories had to pass a pressure tightness test by a panel of 15 to 20 men (requirement did not include women) having a variety of facial shapes and sizes. The pressure tightness test is simply the positive and negative user seal checks that are currently required by the Occupational Safety and Health Administration to be performed each time that a tight fitting respirator is worn by the respirator user to ensure that the respirator is properly seated to the face.

D. Each respirator category had to pass the Coal Dust Test described in the 1934 Schedule 21, in which three men exercise in a room full of coal dust and they passed the test if their face and nostrils showed no more visible coal dust than before the test.

E. Respirators approved as protection against Fumes were equipped with organic vapor cartridges and 15 to 20 men had to pass an isoamyl acetate (banana oil) fit test.

VII. 30 CFR 14, SCHEDULE 21B OF 1965 – SECOND REVISION OF DUST, FUME, AND MIST RESPIRATORS:

A. In 1965, Schedule 21B was published, which included categories of both low efficiency and high efficiency particulate filtering respirators. The facepieces of all respirator categories had to pass a pressure tightness test by a panel of 15 to 20 people having a variety of facial shapes and sizes. As mentioned in the last section, the pressure tightness test is simply positive and negative user seal checks. Also, each respirator category had to pass the Coal Dust Test described earlier. The categories included the following types of particulate respirators:

1. There were three categories of low efficiency respirators approved as protection against Dusts, Fumes, and Mists with TLVs **greater than 0.1 mg/m^3** or 2.4 million particles per cubic foot of air abbreviated as mppcf.

    a. Dusts included asbestos, coal, and silica.

    b. Fumes included antimony, arsenic, manganese, and cadmium.

    c. Mists included chromic acid mist and enamel spray coating.

        i. Tests were the similar as those discussed under the 1934 Schedule 21 approval including a Silica-Dust and Silica-Mist Test.

2. Filters approved for protection against Dusts, Fumes, and Mists with TLVs less than 0.1 mg/m^3 had to pass 90 minute, Lead Dust, Lead Fume, and Chromic Acid Mist Tests.

3. Radionuclides are isotopes that emit radiation resulting in formation of new nuclides. Examples include: uranium and thorium. Respirators approved for protection against radionuclides had to pass a 0.2 micron uranine mechanical test. Uranine is a water soluble yellow-green dye. Respirators approved as protection against radionuclides also had to pass man tests, which included isoamyl acetate fit tests, and DOP quantitative fit tests. (The National Toxicology Program latter found that DOP may be carcinogenic. Corn oil is now used for quantitative fit testing.).

4. The first high efficiency particulate air (HEPA) filters were approved for protection against Dust/Fume/Mist for TLVs **less than 0.1 mg/m^3** or up to 10, 100, or 1,000 times the TLV for radionuclides. Filters were mechanical tested and had to be 99.97 percent efficient against 0.3 micron sized dioctyl phthalate aerosol (DOP). This DOP Filter Test had the same passing criteria as the DOP test for HEPA filters set forth in 30 CFR Part 11, which was promulgated in 1972.

    a. There was an interesting requirement for high efficiency filtered respirators in which the exhalation valve must be provided with a dead-air space or other means to prevent inward leakage of contaminated air during inhalation. Valve covers were required to provide the dead-air space to trap the last portion of exhaled breath in the valve cover. During the next inhalation, any leakage around the exhalation valve would cause this small pocket of exhaled breath surrounding the exhalation valve to be inhaled instead of contaminated air. In contrast, if the exhalation valve cover was missing, the air immediately surrounding the valve would be contaminated workplace air, which would be inhaled if the valve didn't close immediately after exhalation. This requirement was changed in 30 CFR 11 to "Exhalation valves shall be … designed and constructed to prevent inward leakage of contaminated air."

        i. Although the first HEPA filters were approved in 1965, Arthur D. Little designed the first HEPA filter during the WW-II, Manhattan Project for protection against 0.3 microns sized radioactive particles. The condensation of radioactive iodine was considered the most harmful solid particle and was identified as being 0.3 microns in size. 0.3 micron is in the particle size range that penetrates filters most easily.

VIII. 30 CFR 14, AMENDED SCHEDULE 21B OF 1969 – DUST, FUME, AND MIST RESPIRATORS AMENDED:

A. On 19 June 1969, 30 CFR 14, Schedule 21B was modified to include filters for protection against radon daughters. These respirators had to pass a 312 minute, Lead Fume Test. Radon is a radioactive gas, associated with underground mining industries, which decays into polonium, lead, and bismuth radioactive isotopes, which emit alpha particles. Radon daughter particles easily attach to airborne dust, smoke, and mist which are fine enough to reach the deepest parts of the lungs when inhaled.

B. Maximum inhalation pressure and exhalation pressure for other particulate respirators was 50 and 20 mm H_2O, respectively. However respirators approved for radon daughters could not exceed 18 mm H_2O inhalation pressure and the exhalation pressure could not exceed 15 mm H_2O. Decreased inhalation and exhalation pressure requirements were probably required for miners, whose pulmonary functions may already be challenged.

C. This 1969 amendment introduced provisions for approving the first powered air purifying respirators (PAPRs). PAPRs, which greatly reduce breathing resistance, were approved for protection against radon daughters and radon daughters attached to dust, fumes, and mist. PAPRs had to pass the Lead Fume and Silica Dust Tests with air flow through the filters at least 4 cfm for tight fitting facepieces and 6 cfm for helmets and hooded respirators.

IX. 30 CFR PART 11 OF 1972 – COMBINATION OF ALL RESPIRATOR APPROVAL SCHEDULES:

A. In March 1972, 30 CFR Part 14 was replaced by 30 CFR 11, when the National Institute for Occupational Safety and Health (NIOSH) started jointly approving respirators with the Bureau of Mines. The previously separate respirator schedules for SCBA, Airlines, Gas Masks, Chemical Cartridge Respirators, and Particulate Respirators were combined under 30 CFR 11.

B. In 1973, the regulatory portions of the Bureau of Mines were transferred to the Mining Enforcement and Safety Administration (MESA), under the U.S. Department of the Interior and respirator approvals were issued jointly by MESA/NIOSH.

C. In 1977, the regulatory portions of MESA were transferred to the Mine Safety and Health Administration (MSHA) under the U.S. Department of Labor. Approvals were then jointly issued by NIOSH/MSHA.

D. 30 CFR 11 approved categories of both low efficiency and high efficiency dust, fume, and mist respirators; radon daughters, and single use respirators.

1. Low Efficiency Respirators:

    a. Low Efficiency Respirators with replaceable or reusable filters were approved as protection against dusts, or mists, or fumes with permissible exposure limits (PELs) **not less than 0.05 mg/m^3** or 2 mppcf.

b. Approved Dust and/or Mist respirators were 99 percent efficient against particles 0.4 to 0.6 micron sized silica dust or mist.

c. Approved Fume respirators were 99 percent efficient when tested against lead fume, which were smaller than 1 micron.

i. Most manufacturers had their fume filters approved for dust, fumes and mists because if the filters could pass the fume certification tests then they would certainly pass the dust and mist tests. Some also were approved for radon daughters. Some fume grade filters were once approved for protection against asbestos, but their use is no longer permitted under the OSHA asbestos standards.

2. High Efficiency Particulate Air Respirators:

a. 30 CFR 11 approved HEPA respirators as protection against dust, fume, and mists with PELs **less than 0.05 mg/m^3** or 2 mppcf.

b. HEPA respirators were also approved as protection against radionuclides.

c. HEPA filters must be at least 99.97% efficient against 0.3 micron dioctyl phthalate (DOP) particles. They are also tested against silica dust and mist.

i. Mechanical HEPA filters increase the filter's surface area, usually by folding or pleating. Manufacturers must ensure that this does not increase the breathing resistance. Because of increased breathing resistance, HEPA filters could not pass the low breathing resistance requirements for asbestos and radon daughter certification. NIOSH has written letters stating that HEPA filters are intrinsically approved for asbestos and radon daughters.

3. Radon Daughter Respirators - Respirators approved as protection against Radon daughters had to pass the Silica Dust and Silica Mist Tests and they had very low breathing resistance requirements. NIOSH required these respirators to have low breathing resistance because they anticipated that the workers wearing them already had compromised pulmonary functions from previous occupational exposure.

4. Respirators for Asbestos - Asbestos approved Respirators also had the same requirements as those of the Radon daughters including low breathing resistance also because the workers wearing them already had compromised pulmonary functions from previous occupational exposure.

5. Single Use Respirators - Single use (or disposable) respirators were approved as protection against pneumoconiosis and fibrosis producing dusts (Fibrosis is abnormal formation of fibrous (scar) tissue.), or dusts and mists, including, but not limited to aluminum, asbestos, coal, flour, iron ore, and free silica. Some Single use respirators were approved for asbestos but the OSHA Asbestos Standards specifically prohibit using single use dust respirators for asbestos work. The minimum respirator for protection against asbestos is a half mask with HEPA filters.

a. Single-use dust/mist respirators were 99% efficient against silica dust and mist particles 0.4 to 0.6 microns diameter. Single-use could be used until the filter becomes hard to breathe through or the filter is damaged. Then the entire respirator is discarded.

X. 42 CFR 84, OF 1995 – NIOSH RESPIRATOR CERTIFICATION PROCEDURES:

A. Background:

1. On 10 July 1995, the respirator certification regulation, 30 CFR 11, was replaced by 42 CFR 84. Under 42 CFR 84, respirators are approved only by NIOSH except respirators used in underground mining operations, which are required to be approved by both NIOSH and MSHA. Both NIOSH approved and NIOSH/MSHA certified respirators are approved for use. Only the particulate, non-powered air-purifying class of respirators was updated under 42 CFR 84. Manufacturers could sell particulate filters approved under Part 11 until 10 July 1998. Distributors and users could continue to sell and use Part 11 respirators until their supplies were exhausted.

3. The old approval number sequence under 30 CFR 11 for particulate filters is TC-21C-XXXX and had the NIOSH/MSHA emblems. Particulate respirators approved under 42 CFR 84 have the approval number sequence of TC-84A-XXXX and the approval labels bear the NIOSH and Department of Health and Human Services emblems. Chemical cartridge and airline respirators that include particulate filter elements have labels indicating the new particulate filter classification, TC-84A.

B. Classification of Negative Pressure Particulate Respirators:

1. Under 42 CFR 84 there are nine classifications of particulate air purifying respirators. NIOSH now certifies respirators under three classes of filters: N, R, and P and three filter efficiencies: 95, 99, and 100. The filter efficiencies equate to the percentage of particles removed from the air. For example: 95% efficiency means that 95% of the challenge particles are removed and 5% pass through the filter.

2. The 100 filters actually remove 99.97% of the challenge particles - not 100%. OSHA Respirator Standard states that N, R, and P 100 filters are considered HEPA filters. All nine classes can be used as protection against TB in health care facilities.

3. Filters approved under 42 CFR 84 can be used without workplace particle size analysis because NIOSH filter testing criteria simulates the "worst-case" respirator use scenario, which includes:

a. Using non-charged aerosols, which are very rigorous challenge agents for electrostatically charged filters;

b. Testing twenty filters;

c. Challenging the filters with very high air flow through the filters, which simulates an exceptionally high work rate of 85 liters/min for single filters and 42.5 liters/min per filter for pairs of filters;

d. Challenging the filters against a very high loading concentration - the challenge concentration is 200 mg/m^3; and

e. Testing filters against 0.2 micron sized particles, which are in the range of the most filter penetrating sized aerosols (0.1 to 0.4 microns).

4. The classes of filters are largely defined by their degradation in oil aerosols. Oils tend to degrade filter efficiency. Oils are defined as hydrocarbon liquids with high boiling points, high molecular weights, and low vapor pressure. Oil aerosols can consist of mineral, vegetable, animal and synthetic substances that are slippery, combustible, and soluble in organic solvents such as ether but not soluble in water. A partial list of filter degrading oils includes mist from the following oils: alboline; white mineral oil; bayol F; blandlube; drakeol; paraffin oil; liquid petrolatum; water-insoluble petroleum-based cutting oils; heat-treating oil; hydraulic oil; lubricating oil; drawing oil; crystol 325; cable oil; drawing oil; engine oil; heat-treating oils; dioctyl phthalate; corn oil; and transformer oil.

5. N filters are tested against a 0.2 micron sized NaCl aerosol with a 0.075 mass median aerodynamic diameter (MMAD). NaCl is only slightly degrading to the filter. N filters cannot be used in atmospheres containing oil aerosols. N filters have no service time limitation in most workplace settings but in high particulate concentrations the N filters cannot be extended beyond 8 hours unless evaluated by the user to prove that the integrity of the filters does not degrade or that the total mass loading of the filters is less than 200 mg.

6. R filters only have service time limitations when used as protection against oil degrading atmospheres. R filters cannot be extended beyond 8 hours of use in an oil aerosol atmosphere unless evaluated by the user to prove that the integrity of the filters does not degrade or that the total mass loading of the filters is less than 200 mg.

a. Both R and P filters are tested against a 0.2 micron sized DOP aerosol with a 0.185 MMAD.

7. P100 filters were originally approved to be used in oil degrading atmospheres and have no time limitations. However, the NIOSH Respirator User Notice of 2 May 1997 states that long term oil exposure has resulted in the reduction in efficiency of P100 filters to efficiencies much less than P95 filters. NIOSH has requested each manufacturer of P100 filters to establish service time recommendations as part of their user instructions.

C. Filter Change Out Schedules:

1. OSHA does not require establishing change out schedules for particulate respirators. However, since N and R filters must be replaced before 200 mg loading is reached; then change out schedules can be calculated if we know the workplace concentration and the daily breathing volume. NIOSH estimates that a typical worker inhales 10 m^3 of air per day. This equates to a 20 lpm breathing or work rate. This information can be used to determine when N and R filters will become loaded with 200 mg.

a. For example: What is the estimated filter change out schedule for an operation in which the Upper Tolerance Limit ($UTL_{95\%, 95\%}$), was 8 mg/m^3 for total dust (Particulates not otherwise regulated)? The $UTL_{95\%, 95\%}$ is the concentration below which we are 95 percent confident that 95 percent of exposures lie. Since no oil is present, a half mask respirator equipped with N95 filters was selected for protection.

i. Calculate daily filter loading by multiplying 8 mg/m^3 exposure by the 10 m^3 air/day breathing volume. This equals 80 mg/day.

ii. Next calculate how many days it takes to load 200 mg on the filters by dividing 200 mg by 80 mg/day.

b. This equals 2.5 days, therefore, change filters every 2.5 days or earlier if breathing starts to be difficult or filters become damaged or unsanitary. This same logic can be applied to R filters to estimate service life and establish filter change out schedules.

c. If P filters are used, replace them according to respirator manufacture's recommendations.

D. Filter Color Coding:

1. ANSI Z88.7-2001 replaces ANSI K13.1-1973 as the current Color Coding Standard for Air-Purifying Respirator Canisters and Filters. The P100 filters and HEPA filters for powered air purifying respirators are purple. Z88.7 uses the HE abbreviation for "High Efficiency" instead of HEPA. Orange was selected for P95, P99, R95, R99, and R100 filters. Orange was the previous color coding for dust/fume/mist filters. Teal was selected for N95, N99 and N100 filters. Combination chemical cartridges with particulate filters have stripes indicating the type of particulate filter. An abbreviated version of the color coding table in ANSI Z88.7 is provided below in Figure 17.

FIGURE 17
ANSI Z88.7-2001
RESPIRATOR FILTER COLOR CODING

CONTAMINANT(s)	COLOR CODE
Acid gases	White
Organic vapors	Black
Ammonia gas	Green
Ammonia and methyl amine gas	Green
Carbon monoxide gas	Blue
Acid gases and organic vapors	Yellow
Acid gases, ammonia, and organic vapors	Brown
Organic vapors, chlorine, chlorine dioxide, hydrogen chloride, hydrogen fluoride, sulfur dioxide, formaldehyde, hydrogen sulfide (escape only) ammonia, and methyl amine	Pale Brown (Tan)
Acid gases, ammonia, organic vapors, and carbon monoxide	Red
Other vapors and gases or combinations not listed above	Olive
HE (HEPA) for PAPRs	Purple
P100	Purple
P95, P99, R95, R99, R100	Orange
N95, N99, N100	Teal

E. Particulate Capture Mechanisms:

1. On inhalation, particles are drawn into the fibrous filter along with the air they are suspended in. Particles are then trapped by the fibers. The probability that a fiber will capture a particle is dependent on:

a. Fiber size and density

b. Particle size and shape

c. Particle velocity

d. Electrical charge of the particle and filter fiber

2. Filters cannot be designed for 100% efficiency - the breathing resistance would be too great. Consequently, filter design is based on combination of particulate filtration mechanisms. Filters are very efficient at filtering very large particles by sedimentation, impaction and interception and very small particles by diffusion. These mechanisms are illustrated in Figure 18.

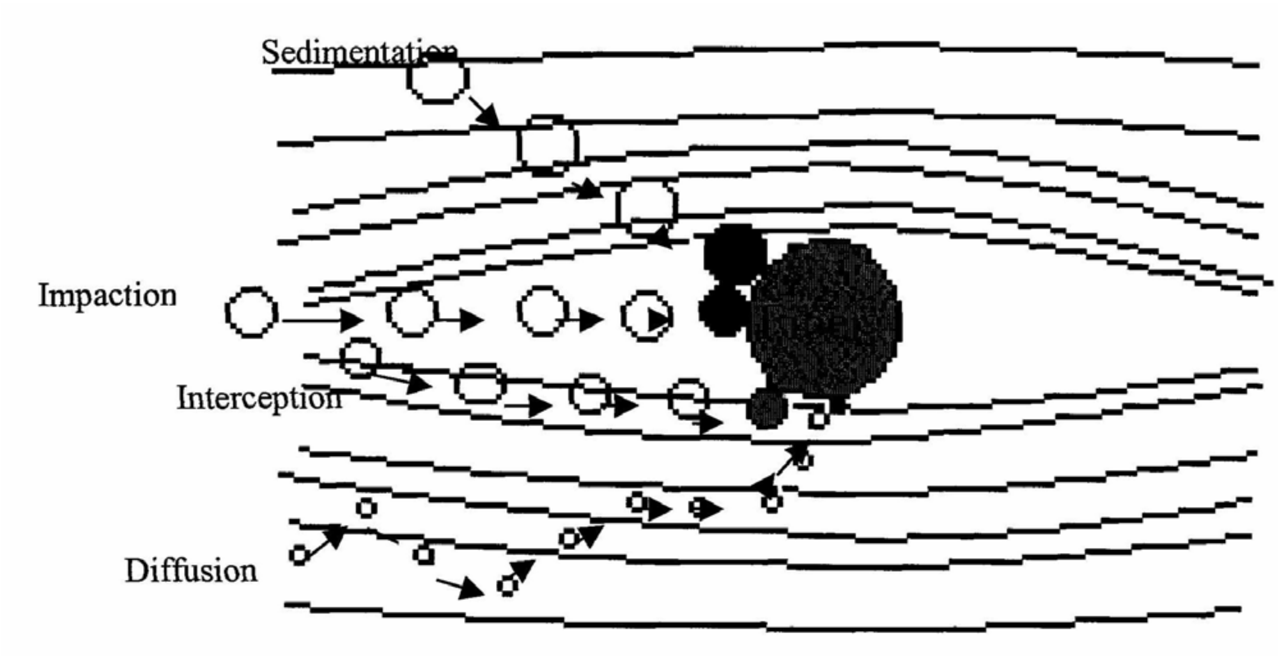


Figure 18

3. Impaction - Particles cannot bend with the airstreams as air goes around the fiber, so the particles impact onto the fiber. Impaction is primarily a function of the particles' momentum or inertia and usually occurs when the airstreams velocity is high; the particles are large (greater than 1 micron diameter) and heavy; and since particles with high mass and velocity have more momentum, it is unlikely that they can turn with the airstreams around the fiber.

4. Interception - Particles stay in the airstreams but are pulled onto the fiber by van der Waal's and electrostatic forces. Interception affects particles between one half and one micron in diameter (lighter in weight than affected by impaction). Generally, particles passing the fiber within a distance of half of the particle diameter will be captured. Filtration efficiency is enhanced by high relative humidity because the moisture forms a liquid meniscus between the particles and fibers, which assures adhesion.

5. Sedimentation - Only large particles (2 microns and above) are affected by sedimentation. Sedimentation works only at low air flow rates. As particles fall through the airstreams by the force of gravity they are captured by the fiber.

6. Diffusion - Smaller particles (less than 0.2 microns diameter) with slower velocities are captured by diffusion. Small particles are subject to Brownian movement - the random movement or bouncing motion of small molecules, almost like vibration, which increases the probability that the particle will contact another object.

a. Slower velocity means the particle remains near the filter for a longer time, which increases the probability that the particle will contact the fiber and be captured. This is the main mechanism in high-efficiency particulate air filters.

7. Electrostatic Attraction - Charged particles in the airstreams are attracted by oppositely charged fibers. Electrostatic attraction is often used to increase filter efficiency. There are two basic methods of establishing electrostatic attraction in filters. The original method consisted of impregnating a blend of wool and synthetic fibers with wood resin, which is then dried and **energized** by a mechanical needling process. This creates a positive charge on the fibers and a negative charge on the resin. Unfortunately, this mechanism is not effective for oil mist or atmospheres with high humidity, which dissipate the electrostatic charge.

a. In the newer method, electret fibers have permanent, strong electrostatic charges embedded inside plastic fibers during processing. Fibers maintain a positive charge on one side and an equally negative charge on the other side. Besides attracting oppositely charged particles to them, electret fibers polarize neutral particles by attracting the oppositely charged dipole to the fiber. They are less affected by high humidity, heat, and oily particles.

F. Filter Efficiency Versus Particle Size:

1. As shown in Figure 19 (Figures 19 through 23 are courtesy of Tom Nelson, from Nelson Industrial Hygiene Services, Inc.), large particles are filtered by impaction and interception, while very small particles are filtered by diffusion. Particles 0.1 to 0.4 microns in size are the most filter penetrating size because these median sized particles are too small for effective interception and too large for effective diffusion filtering mechanisms.

2. Higher efficiency filters don’t necessarily increase protection. NIOSH tests filters under worst case conditions of the most penetrating particle sizes and at a very high flow rate simulating very heavy work that could not be sustained more than brief periods of time. As shown in Figure 20 and explained above, the worst filter efficiency is around 0.2 micron sized particles. However, for particles of this size the filters are still 95% efficient. On either side of the 0.2 micron dip the filters are more than 99% efficient.

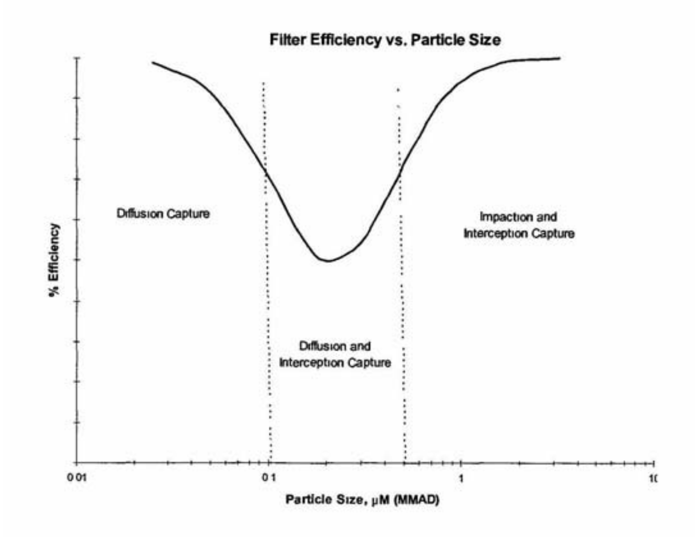


Figure 19

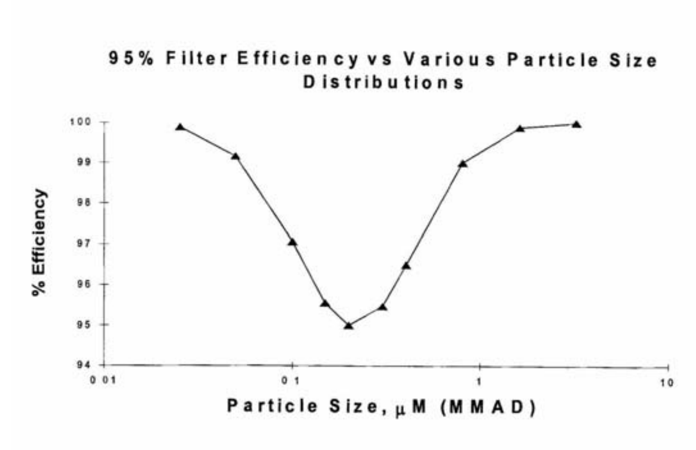


Figure 20

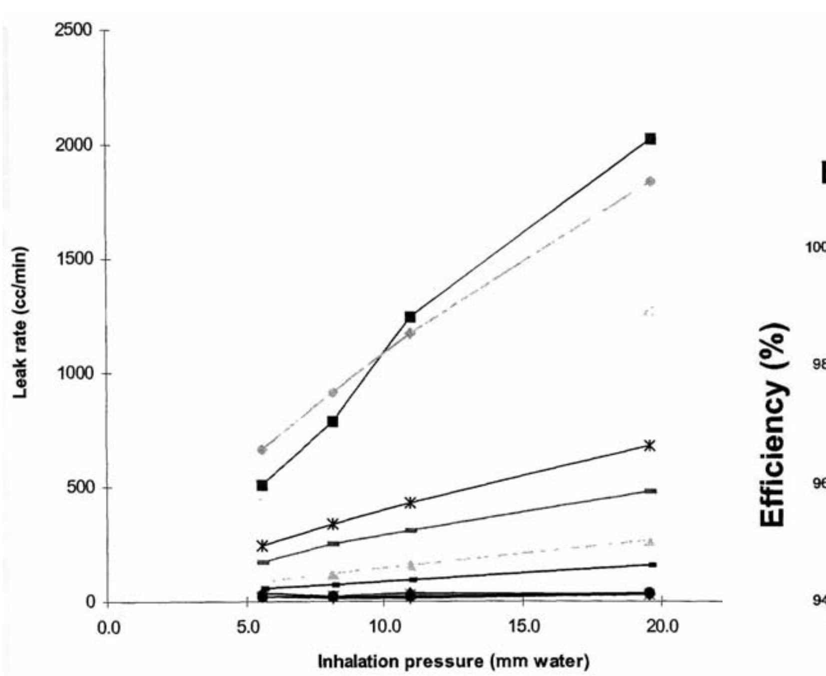


Figure 21

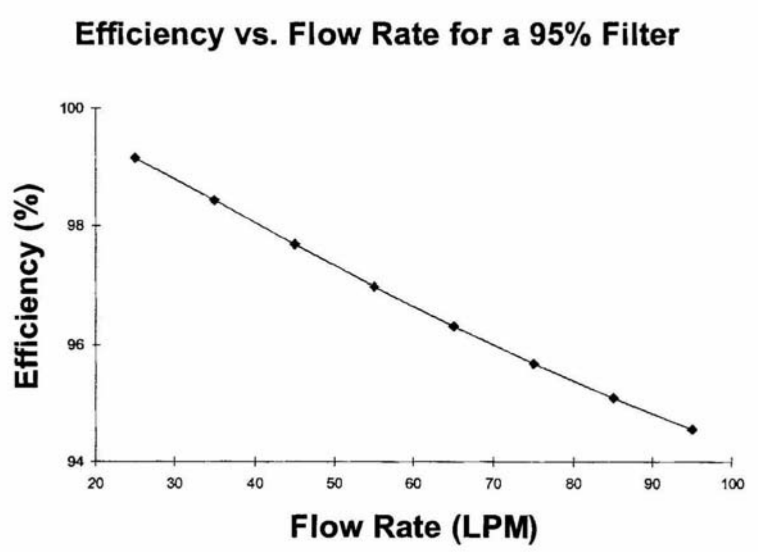


Figure 22

3. Increasing filter efficiency also increases inhalation pressure. The data in Figure 21 was made using a controlled negative pressure fit test apparatus. This data shows that leakage around the facepiece seal increases with increased inhalation pressure.

4. Figure 22 shows that 95 percent filters must be 95 percent efficient to pass NIOSH certification testing at 85 liters per minute (42.5 lpm per filter for pairs of filters). Work

rates realistically expected in the workplace are 20 to 30 lpm. At these workplace breathing rates, Figure 22 shows that 95 percent filters are between 98 to 99% efficient. Figure 23 shows that typical particle size in industry is much larger than the 0.2 micron size that penetrates filters most effectively. These large particles are filtered out with greater than 99% efficiency by 95% filters.

95% Filter- Efficiency by Industry

Industry	Size* (MMAD)	GSD*	%Eff.**
Lead smelter, sintering	11	2.4	100
Lead smelter, furnace	3.3	15.7	99.67
Brass foundry, pouring	2.1	10.3	99.65
Brass foundry, grinding	7.2	12.9	99.73
Woodworking, fine	1.3	2.7	99.70
Woodworking, coarse	33.1	2.6	100
Wood model shop	7.2	1.4	100
Spray painting, lacquer	6.4	3.4	99.95
Spray painting, enamel	5.7	2.0	100

* From Hinds and Bellin: Effect of Facial-seal Leaks on Protection Provided by Half-mask Respirators; Appl. Ind. Hyg. Vol.3 No. 5 May 1988
** Calculated at a moderate work rate, 30 lpm.

Figure 23

5. Because particle sizes in much of industry are large and the work rates commonly encountered in industry are relatively low, 95% filters that pass NIOSH certification testing will be essentially 100% efficient in most workplaces. Using a higher efficiency filter where it is not needed would actually increase exposure by increasing breathing resistance pressure and causing more leakage around the sealing surface. Therefore, carcinogens do not always require HEPA filters.

6. However, hazard analysis must always be performed for respirator selection because there may be scenarios where 100% efficient filters may be necessary. An example of such as a case would be where: 1) the contaminant particle size is the most penetrating; 2) the hazard ratio (concentration of contaminant divided by its occupational exposure limit) is close to the assigned protection factor of the respirator; and 3) the breathing rate is very high. Also, OSHA specifies HEPA filters in many of their chemical specific standards such as lead, asbestos, and cadmium.

G. Guidance for selecting between a 95% filter versus a 100% filter:

1. The following guidance is for selecting filter efficiencies for protection against **0.1 to 0.4 micron sized particles**, which are the most filter penetrating sized particles. The protection provided by a respirator is described by the amount of leakage into the facepiece. Stated mathematically, the protection factor (PF) equals 100 divided by % respirator leakage (PF = 100/ % leakage).

2. An understanding of assigned protection factors (APFs) is necessary before proceeding in this discussion. APFs are defined as the workplace levels of respiratory protection that would be provided by properly functioning and properly used respirators or class of respirators when all elements of an effective respiratory protection program are established and are being enforced. The classes of half mask and full face, negative pressure air-purifying respirators have an APF of 10 and 50, respectively. These APFs equate to 10% leakage for half masks and 2% leakage for full face respirators, assuming that there is 0% filter leakage. To determine filter efficiency needed:

a. First calculate the hazard ratio (HR) to determine what APF is required and therefore what class of respirator is needed (HR = [Exposure]/ OEL);

b. Next rearrange PF equation and calculate leakage for the class of respirator:

(% leakage = 100/ APF)

(% leakage $_{(\text{half mask})}$ = 100/ 10 = 10%) (% leakage $_{(\text{full face})}$ = 100/ 50 = 2%)

c. Then calculate total leakage by adding filter leakage and respirator class leakage. Example:

95% filters have 5% leakage; therefore,
(% leakage (total) = 100/ % leakage (respirator class) + 5% (filter leakage))

d. Finally, calculate protection factor using the total % leakage:

(PF = 100/ % leakage (total))

If PF < HR then a 100% filter is required;
If PF > HR then a 95% filter is sufficient

3. A demonstration of the decision process used to determine the filter efficiency required for inhalation protection against the most filter penetrating sized particles (0.1 to 0.4 micron sized particles) is shown in the following example.

Examples For Selection of 95% Versus 100% Filter	
100% Filter Required	95% Filter is Sufficient
Exposure = 250 ppm, OEL = 15 ppm HR = 250 ppm /15 ppm = 16.7 Must use full face: APF = 50; Leakage = 2% % leakage = 100/ APF % leakage = 100/ 50 = 2% Total % leakage % leakage$_{(\text{total})}$ = 100/ % leakage$_{(\text{respirator class})}$ + 5%$_{(\text{filter leakage})}$ % leakage$_{(\text{total})}$ = 2% + 5% = 7% Recalculate PF (PF = 100/ % leakage$_{(\text{total})}$) PF = 100/ 7% = 14.3 Since PF (14.3) < HR (16.7) use a 100% filter.	Exposure = 50 ppm, OEL = 20 ppm HR = 50 ppm /20 ppm = 2.5 Can use half mask: APF = 10; Leakage = 10% % leakage = 100/ APF % leakage = 100/ 10 = 10% Total % leakage % leakage$_{(\text{total})}$ = 100/ % leakage$_{(\text{respirator class})}$ + 5%$_{(\text{filter leakage})}$ % leakage$_{(\text{total})}$ = 10% + 5% = 15% Recalculate PF (PF = 100/ % leakage$_{(\text{total})}$) PF = 100/ 15% = 6.7 Since PF (6.7) > HR (2.5) use a 95% filter.

H. Respirator Filtration of Nanoparticles:

1. Nanoparticles are very small with diameters less than 100 nm in at least one dimension. Because of their small size, air sampling results indicating low mass concentrations may actually contain very large surface areas of nanoparticles. Nanoparticles may be more biologically reactive than larger particles of similar chemical composition because of their increased surface area and their smaller, more lung penetrating size. Currently, there are no specific exposure limits for nanoparticles although occupational exposure limits exist for larger particles of similar chemical composition.

2. In "Approaches to Safe Nanotechnology," NIOSH provides interim guidance on control technologies, work practices, and personal protective equipment demonstrated to be protective against fine and ultrafine particles. According to single fiber filtration theory, particles larger than 0.3 microns are collected most efficiently by impaction, interception, and gravitational settling, while particles smaller than 0.3 microns (300 nm) are collected most efficiently by diffusion or electrostatic attraction. Penetration of 0.3 micron particles represents the worst case because these particles are considered to be in the range of the most penetrating particle size. However, the most penetrating particle size range for a given respirator can vary based on the type of filter media employed and the condition of the respirator. For example, the most penetrating particle size for electrostatically charged filter media can range from 50–100 nm (0.05 - 0.1 micron). Reference (c) summarizes evidence indicating that the most penetrating size for electret filters may be much less than 100 nm. This article also questions if NIOSH filter certification testing is effective at determining filtration efficiency against aerosols less than 100 nm because the forward light scattering photometry detection method is not capable of adequately measuring the light scatter of such small particles.

3. As stated in "Approaches to Safe Nanotechnology," filter filtration efficiency increases as particle size decreases below the most penetrating particle size (300 nm) to the point when particles are so small that they behave like vapor molecules and may literally bounce through a filter by what is described by the "thermal rebound theory." In NIOSH's ongoing respirator filter media research of particles in the 3–100 nm range, they observed that penetration of nanoparticles through filter media decreased down to 3 nm as expected by traditional filtration theory and no evidence for thermal rebound of nanoparticles in the size ranges was found. Therefore, NIOSH stated that, based on these preliminary findings, NIOSH certified respirators should provide the expected levels of protection if properly selected and fit tested as part of a complete respiratory protection program.

4. Nanoparticle filtration research is ongoing and NIOSH has dedicated the following website to post findings of this research as results become available: NIOSH Nanotechnology Website

I. Respiratory Protection Against Pandemic Influenza:

1. All nine classes of NIOSH approved particulate respirator filters can be used as protection against microorganisms (e.g., anthrax, tuberculosis, and avian influenza H5N1 viruses). At the breathing rates found in the workplace, 95% efficient filters filter out

more than 99.5% of these microorganisms. Figure 24 shows the efficiency of N95 filters at removing microorganisms of various size ranges.

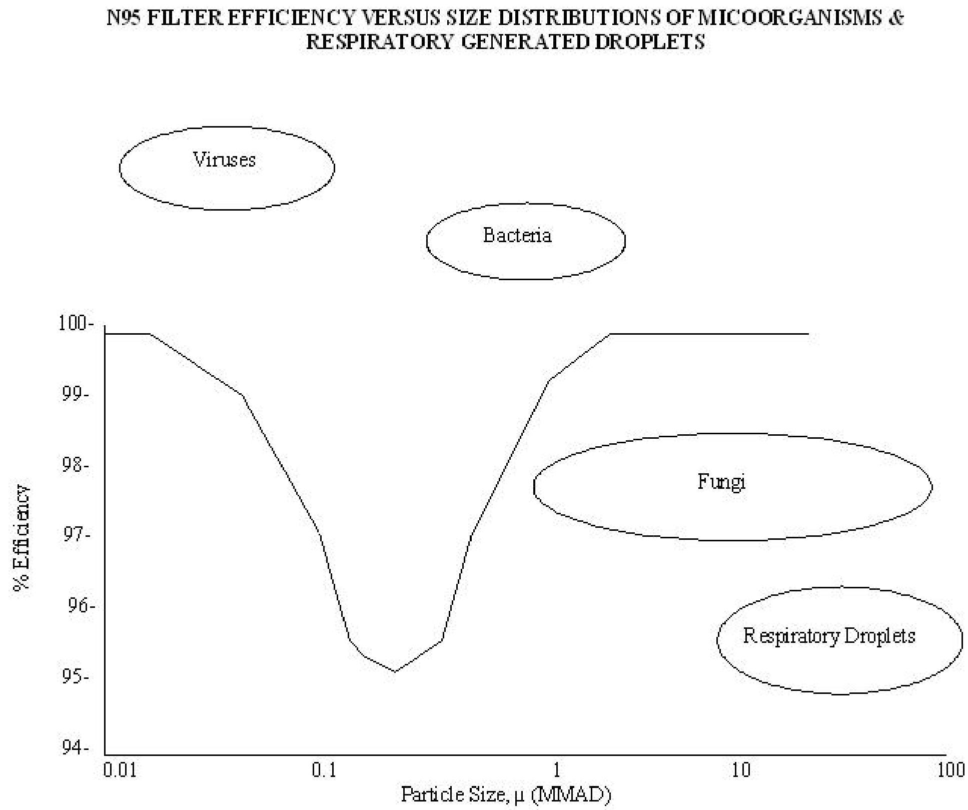


Figure 24

2. N95 filter media is the minimal protective filter recommended for protection against pandemic influenza. N95 filter media will effectively filter out 10 to 100 micron sized virus laden droplets produced by the respiratory tract and also viruses, which are much smaller in size (0.08 to 0.12 microns). According to reference (d), a sneeze generates nearly 2 million droplets, which can be expelled at nearly 200 miles per hour and a cough produces approximately 100,000 droplets. N95 filter media is available both as replaceable filters for elastomeric respirators and is also the integral portion of filtering facepiece respirators.

3. Although N95 filtering media is an effective filter, protection against inhalation of influenza aerosols is also dependent on how well the respirator seals to the face to prevent leakage. Lawrence, et. al., (reference (e)) compared the performance of surgical masks, N95 filtering facepiece respirators, and elastomeric half mask respirators equipped with N95 filtering media. They determined that surgical masks both as a class and individually provided very little protection and that filtering facepiece respirators do not perform as well as elastomeric half masks. They also determined that passing fit-testing resulted in a higher level of protection when compared with no fit testing for both filtering facepiece and elastomeric respirators.

4. Lawrence, et. al., stated that differences in design features could be the reason elastomeric half-facepiece respirators as a whole provided a higher level of protection than the filtering-facepiece respirators. They explained that all of the elastomeric respirators were equipped with adjustable head straps, whereas some of the filtering-facepiece respirators had only elastic, nonadjustable straps.

5. The minimum respiratory protection required for protection against Pandemic Influenza is a properly fitting N95 filtering facepiece respirator. There is a wide spectrum of filtering facepiece designs. Many are poorly designed and do not fit the wearer very well. In some cases the whole facepiece consists of filter media. However, many are very well designed and some even include a sealing surface to ensure a tight seal with the face. Also, if filtering facepiece respirators are selected for use, select cup shaped filtering facepieces with good sealing surfaces that can pass fit testing and meaningful user seal checks. The NAVMCPUBHLTHCEN developed the *NAVY POCKET GUIDE FOR HEALTH CARE PROVIDERS - PANDEMIC INFLUENZA PROTECTION PROCEDURES* based on the best practices prescribed in the plethora of information on pandemic influenza and control of tuberculosis and other infectious diseases and is available under the NAVMCPUBHLTHCEN "Industrial Hygiene" homepage.

6. An adequate amount of sizes and numbers of respirators must be stored to ensure that when needed, there will be sufficient quantities on hand for personnel required to wear them and that they will correctly fit the users. As with all respirators, stockpiles of stored respirators must be maintained in pristine condition.

XI. WELDING SPARK RESISTANT FILTERS:

A. There is special matter that must be taken into consideration during the process of respirator selection for welding operations, which is the sparks produced during welding can enter filters and set the filtering media on fire (Figure 25). Respirator manufacturers make specially designed filters to prevent sparks from entering into the filter media. There are also plenum respirators with the filters worn on the back to avoid sparks.

Figure 25

XII. REFERENCES:

a. U.S. Department of Labor, Mine Safety and Health Administration**,** Mining History, Museums and Disasters website http://www.msha.gov/history.htm

b. Held, Bruce J.: History of Respiratory Protective Devices in the U.S., University of California, Lawrence Livermore Laboratory, California (Written under the U. S. Energy

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